# SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

| FORM 1  | 0-Q   |
|---|---|
| ☑ QUARTERLY REPORT PURSUANT TO SECTION 13   | OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934                   |
| For the quarterly period ende   | d <b>January 31, 2002</b>   |
| ☐ TRANSITION REPORT PURSUANT TO SECTION 13  | OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934                   |
| For the transition period from  | to  |
| Commission File Num   | ber <b>001-15167</b>  |
| BIOPURE CORI  |   |
| (Exact name of registrant as  | specified in its charter)   |
| Delaware  | 04-2836871  |
| (State of Incorporation)  | (IRS Employer Identification Number)                              |
| 11 Hurley Street, Cambridge, Massachusetts  | 02141   |
| (Address of principal executive offices)  | (Zip Code)  |
| (617) 234-6<br>(Registrant's teleph   |   |
|   |   |
| Indicate by check mark whether the registrant (1) has filed all reports req Exchange Act of 1934 during the preceding 12 months (or for such short and (2) has been subject to such filing requirements for the past 90 days. | er period that the registrant was required to file such reports), |

The number of shares outstanding of each of the issuer's classes of common stock as of February 28, 2002 was:

Class A Common Stock, \$.01 par value 25,744,456 Class B Common Stock, \$1.00 par value 117.7

## **TABLE OF CONTENTS**

Condensed Consolidated Balance Sheets

Condensed Consolidated Statements of Operations

Condensed Consolidated Statements of Cash Flows

Notes to Condensed Consolidated Financial Statements

Independent Accountants' Review Report

Management's Discussion and Analysis of Financial Condition and Results of Operations

Quantitative and Qualitative Disclosure About Market Risk

Part II — Other Information

Item 1. Legal Proceedings

Item 2. Changes in Securities and Use of Proceeds

Item 6. Exhibits and Reports on Form 8-K

**SIGNATURES** 

**EXHIBIT INDEX** 

Ex-15 Acknowledgement Letter of Ernst & Young LLP

Ex-99 Risk Factors

# INDEX TO FORM 10-Q

|  | Page |
|--|------|
| Part I — Financial Information:  |      |
| Item 1 - Financial Statements (Unaudited)  |      |
| Condensed Consolidated Balance Sheets at January 31, 2002 and October 31, 2001                                   | 1    |
| Condensed Consolidated Statements of Operations for the quarters ended January 31, 2002 and January 31, 2001     | 2    |
| Condensed Consolidated Statements of Cash Flows for the three months ended January 31, 2002 and January 31, 2001 | 3    |
| Notes to Condensed Consolidated Financial Statements   | 4-6  |
| Independent Accountants' Review Report   | 7    |
| Item 2 - Management's Discussion and Analysis of Financial Condition and Results of                              |      |
| Operations   | 8-12 |
| Item 3 - Quantitative and Qualitative Disclosure of Market Risk  | 12   |
| Part II — Other Information:   |      |
| Item 1 –Legal Proceedings  | 13   |
| Item 2 – Changes in Securities and Use of Proceeds   | 13   |
| Item 6 – Exhibits and Reports on Form 8-K  | 13   |
| Signatures   | 14   |
| Exhibit Index  |      |

Biopure®, Hemopure® and Oxyglobin® are registered trademarks of Biopure Corporation.

# Condensed Consolidated Balance Sheets (In thousands, except share and per share data) (Unaudited)

| Assets:   | January 31, 2002 | October 31, 2001 |
|---|------------------|------------------|
| Current assets:   |                  |                  |
| Cash and cash equivalents   | \$ 33,389        | \$ 36,089        |
| Accounts receivable, net  | 459              | 724              |
| Inventories, net  | 3,935            | 4,665            |
| Other current assets  | 699              | 771              |
|   |                  |                  |
| Total current assets  | 38,482           | 42,249           |
| Property, plant and equipment, net  | 34,169           | 30,162           |
| Other assets  | 11,695           | 11,776           |
| Total assets  | \$ 84,346        | \$ 84,187        |
|   |                  |                  |
| Liabilities and stockholders' equity:   |                  |                  |
| Current liabilities:  |                  |                  |
| Accounts payable  | \$ 847           | \$ 1,348         |
| Accrued expenses  | 4,982            | 4,949            |
|   |                  |                  |
| Total current liabilities   | 5,829            | 6,297            |
| Long-term debt  | 8,364            | 5,205            |
| Deferred compensation   | 1,810            | 1,792            |
| Total long-term liabilities   | 10,174           | 6,997            |
| Stockholders' equity:   |                  |                  |
| Preferred stock, \$0.01 par value, 30,000,000 shares authorized, no shares outstanding  | _                | _                |
| Common stock:   |                  |                  |
| Class A, \$0.01 par value, 100,000,000 shares authorized, 25,744,456 shares outstanding at January 31, 2002 and 25,225,083 at |                  |                  |
| October 31, 2001  | 257              | 252              |
| Class B, \$1.00 par value, 179 shares authorized, 117.7 shares outstanding  | _                | _                |
| Capital in excess of par value  | 390,642          | 383,570          |
| Contributed capital   | 24,574           | 24,574           |
| Notes receivable  | (1,593)          | (1,655)          |
| Accumulated deficit   | (345,537)        | (335,848)        |
| Total stockholders' equity  | 68,343           | 70,893           |
| Total liabilities and stockholders' equity  | \$ 84,346        | \$ 84,187        |

Note: The balance sheet at October 31, 2001 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

# Condensed Consolidated Statements of Operations (In thousands, except share and per share data) (Unaudited)

Three Months Ended

|   | Tillee Months Ended |                  |
|---|---------------------|------------------|
|   | January 31, 2002    | January 31, 2001 |
| Revenues:   |                     |                  |
| Oxyglobin   | \$ 728              | \$ 731           |
| Other   | _                   | 4                |
| Tatal   | 729                 | 725              |
| Total revenues  | 728                 | 735              |
| Cost of revenues  | 827                 | 770              |
| Gross profit (loss)   | (99)                | (35)             |
| Operating expenses:   |                     |                  |
| Research and development  | 6,972               | 8,187            |
| Sales and marketing   | 463                 | 622              |
| General and administrative  | 2,605               | 3,073            |
| Total operating expenses  | 10,040              | 11,882           |
| Loss from operations  | (10,139)            | (11,917)         |
| Other income, net   | 450                 | 1,316            |
| Net loss  | \$ (9,689)          | \$(10,601)       |
| Per share data:   |                     |                  |
| Basic net loss per common share   | \$ (0.38)           | \$ (0.42)        |
| Weighted-average shares used in computing basic net loss per common share | 25,401              | 24,960           |
| custo not 1000 per common sinute  | 23,101              | 21,500           |

See accompanying notes.

# Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

|   | Three Months Ended |                  |
|---|--------------------|------------------|
|   | January 31, 2002   | January 31, 2001 |
| Operating activities:   |                    |                  |
| Net loss  | \$ (9,689)         | \$(10,601)       |
| Adjustments to reconcile net loss to net cash used in operating activities:             |                    |                  |
| Depreciation and amortization   | 1,009              | 998              |
| Equity compensation   | (145)              | 1,347            |
| Deferred compensation   | 18                 | 18               |
| Accrued interest on stockholders' notes receivable                                      | (18)               | (28)             |
| Changes in assets and liabilities:  |                    |                  |
| Accounts receivable   | 265                | 57               |
| Inventories   | 730                | (432)            |
| Other current assets  | 72                 | (28)             |
| Accounts payable  | (501)              | (1,423)          |
| Accrued expenses  | 32                 | (304)            |
|   |                    |                  |
| Net cash used in operating activities   | (8,227)            | (10,396)         |
| Investing activities:   |                    |                  |
| Purchase of property, plant and equipment   | (1,843)            | (934)            |
| Other assets  | (1)                | 21               |
|   |                    |                  |
| Net cash used in investing activities   | (1,844)            | (913)            |
| Financing activities:   |                    |                  |
| Proceeds from sale of common stock  | 7,250              | _                |
| Payment of notes receivable from stockholders   | 80                 | 337              |
| Proceeds from exercise of options and warrants  | 41                 | 73               |
| Net cash provided by financing activities   | 7,371              | 410              |
| Net decrease in cash and cash equivalents   | (2,700)            | (10,899)         |
| Cash and cash equivalents at beginning of period  | 36,089             | 88,828           |
| Cash and cash equivalents at end of period  | \$33,389           | \$ 77,929        |
| Non-cash transactions:  |                    |                  |
| New facility construction financed through capital lease (classified as long-term debt) | \$ 3,159           | \$ —             |

See accompanying notes.

Notes to Condensed Consolidated Financial Statements January 31, 2002 (Unaudited)

## 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three month period ended January 31, 2002 are not necessarily indicative of the results that may be expected for the year ending October 31, 2002.

The Company has financed operations from inception primarily through sales of equity securities, development and license agreement payments, interest income and debt. The Company has not been profitable since inception and had an accumulated deficit of \$345,537,000 as of January 31, 2002. Management expects that the Company will continue to generate losses from operations for the foreseeable future. The Company will explore and is pursuing opportunities to raise capital through sales of equity and debt securities, potential partnerships, bank borrowings or leasing arrangements.

For further information, refer to the consolidated financial statements and footnotes thereto, included in the Company's Annual Report on Form 10-K for the year ended October 31, 2001.

# 2. Net Loss per Share

Basic net loss per common share is computed based on the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed based upon the weighted-average number of common shares outstanding during the year, adjusted for the dilutive effect of shares issuable upon the conversion of preferred stock outstanding and the exercise of common stock options and warrants determined based upon the average market price of common stock for the period. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

#### 3. Inventories

Inventories are valued at the lower of cost (determined using the first-in, first-out method) or market. Inventories were as follows:

|                          | January 31, 2002 | October 31, 2001 |
|--------------------------|------------------|------------------|
| In thousands             |                  |                  |
| Raw materials            | \$ 935           | \$ 771           |
| Work-in-process          | 94               | 243              |
| Finished goods-Oxyglobin | 1,222            | 1,886            |
| Finished goods-Hemopure  | 1,684            | 1,765            |
|                          |                  |                  |
|                          | \$3,935          | \$4,665          |
|                          |                  |                  |

Notes to Condensed Consolidated Financial Statements January 31, 2002 (Unaudited) (Continued)

# 4. Accrued Expenses

Accrued expenses consisted of the following:

|   | January 31, 2002 | October 31, 2001 |
|---|------------------|------------------|
| In thousands                                  |                  |                  |
| Clinical trials                               | 558              | 662              |
| Preparation of biologic license application   | 502              | 306              |
| Capacity upgrade                              | 513              | 375              |
| Accrued payroll and related employee expenses | 1,390            | 1,365            |
| Accrued vacation                              | 387              | 398              |
| Other   | 1,632            | 1,843            |
|   |                  |                  |
|   | \$4,982          | \$4,949          |
|   |                  |                  |

## 5. Stock Compensation

In October 2000 and April 2001, Biopure granted 30,000 options to each of two consultants, for a total of 60,000 options, which must be accounted for at fair value, pursuant to Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (SFAS 123) and EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services". The Company records compensation expense based on a service period adjusted for the fair value of the stock until these options have been earned, as discussed below.

With respect to these 60,000 options, 15,000 have been earned as of January 31, 2002. With respect to the remaining 45,000 options, the Company recorded a reduction to non-cash compensation expense of \$145,000 for the quarter ended January 31, 2002 because the closing price of Biopure common stock on January 31, 2002 was lower than on October 31, 2001.

## 6. Commitment

In December 2001, the Company signed an amended letter of intent for the construction and financing of a new 500,000 unit Hemopure plant in South Carolina. The new plant is expected to cost approximately \$120,000,000, up from \$85,000,000, and is expected to be financed through a capital lease. As such, the financial statements include property, plant & equipment and offsetting debt. During 2001, Biopure paid \$10,000,000 into an escrow account, which has been recorded as a deposit in long-term assets. These escrow funds, constituting the Company's cash contribution during the construction phase of the new facility, are being used to fund initial expenditures for the new facility. Under the agreement, the \$10,000,000 in project cost funded by Biopure will be refunded upon receipt of approval of Hemopure by the United States Food and Drug Administration (FDA) and if a formal

Notes to Condensed Consolidated Financial Statements
January 31, 2002
(Unaudited)
(Continued)

lease agreement has been executed. If FDA approval is not received, the \$10,000,000 deposit will not be returned to the Company and will be treated as a capital expenditure, subject to an immediate impairment review pursuant to SFAS No. 121, "Accounting for Long-Lived Assets and for Long-Lived Assets to Be Disposed Of". As of January 31, 2002, \$8,364,000 has been included in property, plant and equipment and long term debt reflecting expenditures to date for the engineering and design costs of the facility. A lease for the South Carolina facility has not been signed.

# 7. Financing Activities

Biopure is a party to a \$75,000,000 equity line stock purchase agreement with Société Générale. Under this agreement, Biopure has the option of drawing up to a balance (as of January 31, 2002) of \$67,750,000 until June 2003, subject to certain limitations, in exchange for the issuance of Biopure common stock. The primary limitation on use of the line is a minimum trading price for our common stock of \$13 per share, unless waived. The maximum size of each drawdown may be up to \$3,000,000 in a five-day drawdown period or up to \$4,500,000 if the average daily dollar trading volume of the Company's common stock increases to \$7,500,000. The Company is under no obligation to draw down funds and as of January 31, 2002 has drawn \$7,250,000 under this agreement. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price specified in the agreement.

On March 11, 2002, the Company filed a \$30,000,000 common stock shelf registration statement with the SEC to facilitate future financings. The registration statement has been declared effective by the SEC.

## 8. Capital Transactions

During the first quarter of fiscal 2002, Biopure issued 516,531 shares of common stock in connection with the Société Générale equity line stock purchase agreement, described in Note 7, for proceeds of \$7,250,000.

## 9. Litigation

As of March 15, 2002, Biopure and its Chairman and Chief Executive Officer were named as defendants in five related cases filed on February 5, 2002, February 22, 2002, March 15, 2002 and two on March 12, 2002, respectively, in the U.S. District Court for the District of Massachusetts (the "Court") by alleged purchasers of Biopure's common stock, purporting to be class actions. The lawsuits claim that Biopure violated the federal securities laws by publicly disseminating materially false and misleading statements regarding the anticipated timing of a biologic license application Biopure expected to make to the U.S. Food and Drug Administration, resulting in the artificial inflation of Biopure's common stock price during the purported class period between May 8, 2001 through December 6, 2001. The complaints do not specify the amount of alleged damages plaintiffs seek to recover. Defendants have filed motions to dismiss the complaints and believe that the lawsuits are without merit and intend to defend them vigorously. At this time, the Company cannot estimate what impact, if any, these cases may have on the financial statements.

Independent Accountants' Review Report

The Board of Directors Biopure Corporation

We have reviewed the accompanying condensed consolidated balance sheet of Biopure Corporation (the Company) and subsidiaries as of January 31, 2002, and the related condensed consolidated statements of operations and the condensed consolidated statements of cash flows for the three-month periods ended January 31, 2002 and 2001. These financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures to financial data, and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with auditing standards generally accepted in the United States, which will be performed for the full year with the objective of expressing an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying condensed consolidated financial statements referred to above for them to be in conformity with accounting principles generally accepted in the United States.

We have previously audited, in accordance with auditing standards generally accepted in the United States, the consolidated balance sheet of the Company as of October 31, 2001, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended (not presented herein) and in our report dated December 10, 2001 (except for Note 14, as to which the date is January 22, 2002), we expressed an unqualified opinion on those consolidated financial statements. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of October 31, 2001, is fairly stated, in all material respects, in relation to the consolidated balance sheet from which it has been derived.

/s/ Ernst & Young LLP

Boston, Massachusetts March 13, 2002

Management's Discussion and Analysis of Financial Condition and Results of Operations January 31, 2002

Cautionary Statement Regarding Forward-Looking Information

The following discussion of our financial condition and results of operations should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes included elsewhere in this report. Except for strictly historical information contained herein, matters discussed in this report constitute forward-looking statements. When used herein, the words "expects," "estimates," "intends," "plans," "should", "anticipates" and similar expressions are intended to identify such forward-looking statements. Actual results could differ materially from those set forth in the forward-looking statements. There can be no assurance that Biopure will be able to commercially develop its oxygen therapeutic products, that necessary regulatory approvals will be obtained, that anticipated milestones will be met in the expected timetable, that any clinical trials will be successful, or that any approved product will attain market acceptance and be sold in the quantities anticipated. Actual results may differ from those projected in forward-looking statements due to risks and uncertainties that exist in the Company's operations and business environment. These risks include, without limitation, the Company's stage of product development, history of operating losses, accumulating deficits, and uncertainties and possible delays related to clinical trials, regulatory approvals, possible healthcare reform, manufacturing capacity, market acceptance, competition and the availability of sufficient financing to support operations. In light of the substantial risks and uncertainties inherent in all future projections, the inclusion of forward-looking statements in this report should not be regarded as representations by the Company that the objectives or plans of the Company will be achieved. The Company undertakes no obligation to release publicly the results of revisions to these forward-looking statements to reflect events or circumstances after the date hereof. Reference is made in particular to the risk factors set forth in Exhibit 99 to this report and the discussions set forth below in this report under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

## Overview

We are a leading developer, manufacturer and supplier of a new class of pharmaceuticals, called oxygen therapeutics. Our oxygen therapeutics are pharmaceuticals that one administers intravenously into the circulatory system to increase oxygen delivery to the body's tissues. We have developed and manufacture, using a proprietary process and patented technology, two hemoglobin-based oxygen carriers. Two pivotal Phase III clinical trials have been completed for Hemopure and are expected to be the basis for our application to the FDA for marketing approval in the United States. In fiscal 2001, Hemopure was approved in South Africa for use in adult patients undergoing elective surgery to treat acute anemia and eliminate, reduce or delay red blood cell transfusion. Oxyglobin, for veterinary use, is the only hemoglobin-based oxygen carrier approved by the FDA and the European Medicines Evaluation Agency.

Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financings, strategic corporate alliances, licensing agreements and interest income. We have not been profitable since inception and had an accumulated deficit of \$345,537,000 as of January 31, 2002. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure and pre-marketing expenditures for Hemopure. We began generating revenue from the sale of Oxyglobin in fiscal 1998.

Management's Discussion and Analysis of Financial Condition and Results of Operations January 31, 2002 (continued)

We believe our cash and cash equivalents, as of January 31, 2002, are sufficient to fund our current plan into the first quarter of fiscal 2003. Under this plan our operations for the balance of fiscal 2002 will be in support of our application to the FDA for marketing approval of Hemopure, the capacity upgrade of our Cambridge manufacturing facility, sales to South Africa and sales of Oxyglobin. Efforts for development of additional indications for Hemopure and for preparation to market Hemopure in the United States will be deferred until additional funds are available.

## Critical Accounting Policies

SFAS 121 (and SFAS 144, when applicable) requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Our investments in property and equipment, including construction in progress and the new facility construction; license agreements related to the source of supply of a major raw material; and the deposit related to the initial new facility project costs are the principal long-lived assets that could be subject to such a review. The events or changes in circumstances, among others, that may result in an impairment of these assets are a significant delay in expected regulatory approvals for our products; a change in the source of supply of the major raw material; or a significant reduction in the demand for our products.

## **Results of Operations**

Three months ended January 31, 2002 compared to three months ended January 31, 2001

Total revenues, consisting entirely of Oxyglobin sales, were \$728,000 for the first quarter of fiscal 2002, compared with \$735,000 for the corresponding period in 2001. European sales were \$65,000 for the first quarter of fiscal 2002. Oxyglobin was first sold into Europe during the second quarter of fiscal 2001. Domestic sales decreased 9.3%, to \$663,000, compared to the same period last year. This decrease reflects a 4.8% increase in average selling price and an 11.6% decrease in the units shipped. Our Cambridge manufacturing facility was shut down in November 2001 for capacity expansion. Biopure has reduced its veterinarian educational programs, in an effort to ensure sufficient supply, during this temporary six-month shutdown.

Cost of revenues increased 7.4% to \$827,000 in the first quarter of fiscal 2002 primarily due to an increase in the unabsorbed fixed manufacturing costs, incurred during the Cambridge facility shutdown, allocated to cost of revenues for Oxyglobin. Cost of revenues includes the direct costs associated with the production of Oxyglobin plus an allocation of a portion of the unabsorbed fixed costs of manufacturing. The remainder of these unabsorbed fixed costs, incurred during the Cambridge facility shutdown, was allocated to research and development. The above allocations are based on current and expected production levels and annual production capacities and require management judgment.

Management's Discussion and Analysis of Financial Condition and Results of Operations January 31, 2002 (Continued)

Research and development expenses include product and process development and engineering, pre-clinical studies, clinical trials, clinical trial materials and an allocation of unabsorbed fixed costs of manufacturing. Our research and development efforts have been focused on developing and gaining regulatory approval of Hemopure, our product for use in humans. These efforts are now focused on the preparation of our biologic license application to be filed with the FDA. The development and approval of Oxyglobin, our veterinary product, was a result of the development of Hemopure. Hemopure is approved for use in South Africa. Failure to gain one or more additional regulatory approvals during the next several years would make it difficult for the Company to continue its development efforts.

Research and development expenses decreased 14.8% to \$6,972,000 for the first quarter of fiscal 2002, compared to the first quarter of fiscal 2001. The decrease is primarily due to reduced expenses for the U.S. pivotal Phase III clinical trial of Hemopure. During the first quarter of fiscal 2001, there were significant expenses for the monitoring and closing of clinical sites and for the Safety Endpoint Evaluation Committee (SEEC). In the first quarter of fiscal 2002, expenses for other clinical trials and pre-clinical work for additional Hemopure applications also decreased. Expenses in preparation for the filing of a biologic license application with the FDA, in mid-calendar 2002, and the unabsorbed fixed manufacturing costs allocated to research and development both increased.

Sales and marketing expenses, consisting of Oxyglobin expenses, decreased 25.6% to \$463,000 for the first quarter of fiscal 2002. This decrease was primarily due to reductions in veterinarian educational programs designed to reduce demand and ensure sufficient supply during the Cambridge manufacturing facility shutdown. Marketing expenses for Hemopure, currently classified as general and administrative expenses because there are no Hemopure revenues, are expected to be included as sales and marketing expenses in the third quarter of fiscal 2002 when sales to South Africa are expected to begin.

General and administrative expenses decreased 15.2% to \$2,605,000 for the first quarter of fiscal 2002 compared to the same period in 2001. This decrease is primarily due to a credit to general and administrative expenses for non-cash compensation, related to stock option awards, for non-employees of \$145,000 compared to an expense of \$1,347,000 for the same period last year. This non-cash compensation is accounted for as a credit instead of an expense because the closing price of Biopure common stock on January 31, 2002 was lower than on October 31, 2001. Expenses for South Africa marketing activities, consulting, information technology and occupancy costs, increased compared to the first quarter of fiscal 2001.

Other income was \$450,000 in the first quarter of fiscal 2002, compared to \$1,316,000 in the first quarter of fiscal 2001. This decrease reflects the Company's decreased cash balance and lower interest rates. Included in other income for the first quarter of 2002 is \$238,000 that we received as a contingent payment for a 1998 intellectual property transfer not related to Hemopure or Oxyglobin.

## Liquidity and Capital Resources

At January 31, 2002, we had \$33,389,000 in cash and cash equivalents including \$7,250,000 we raised through the sale of equity in the first quarter of fiscal 2002 as discussed below. Based on our fiscal 2002 operating plan,

Management's Discussion and Analysis of Financial Condition and Results of Operations January 31, 2002 (Continued)

we require cash of approximately \$26,000,000 for the remainder of fiscal 2002 to complete the capacity upgrade of our Cambridge manufacturing facility, support the filing of our biologic license application with the FDA, to support our launch of Hemopure in South Africa and to support our Oxyglobin business. We believe our cash and cash equivalents, at January 31, 2002, should be sufficient to fund our current plan into the first quarter of fiscal 2003. Cash requirements are expected to be higher during the first half of fiscal 2002 because of cash that will be used to pay for the Cambridge capacity upgrade and prior to the start of Hemopure sales to South Africa. The cash and cash equivalents do not include the \$10,000,000 placed in escrow for the South Carolina facility as discussed below. Biopure's cash reserves plus the Société Générale financing, if we are able to fully draw and do so, could fund operations through fiscal 2003 under the Company's current operating plan. Expenditures, including the costs of additional personnel, for research and clinical development of additional indications for Hemopure and most expenditures in preparation for marketing and sales of Hemopure in the U.S., will be deferred until sufficient funds, in addition to those on hand, are available. Should management's plans not develop as anticipated, the Company will restrict certain of its planned activities and operations, as necessary, to sustain operations and conserve cash resources. Our cash requirements and our forecast of the period of time through which our financial resources would be adequate to support our operations may vary significantly from current projections and actual results may vary.

In December 2001, the Company signed an amended letter of intent for the construction and financing of a new 500,000 unit Hemopure plant in South Carolina expected to cost \$120,000,000. During fiscal 2001, we paid \$10,000,000, Biopure's contribution to the cost of the facility, into an escrow account to be used to fund certain initial expenditures related to the construction of the new facility. Under the proposed agreement for the construction and financing of the new plant, the \$10,000,000 in project cost funded by Biopure will be refunded upon receipt of FDA approval for Hemopure. The \$10,000,000 has been accounted for as a deposit in long-term assets. If FDA approval is not received, the \$10,000,000 deposit will not be returned to the Company and will be treated as a capital expenditure, subject to immediate impairment review pursuant to SFAS No. 121 (and SFAS 144, when applicable). As of January 31, 2002, \$8,364,000 has been included in property, plant and equipment and long term debt reflecting expenses to date for the engineering of the facility paid from the escrow.

In fiscal 2001, based on the approval of Hemopure in South Africa, Biopure began including Hemopure units in inventory, as these units are saleable. However, we do not expect revenues for Hemopure until the third fiscal quarter. The unit value in inventory is less than the expected unit sales price.

Biopure is a party to a \$75,000,000 equity line stock purchase agreement with Société Générale. Under this agreement, Biopure has the option of drawing up to a balance (as of January 31, 2002) of \$67,750,000 until June 2003, subject to certain limitations, in exchange for the issuance of Biopure common stock. The primary limitation on use of the line is a minimum trading price for our common stock of \$13 per share, unless waived. The maximum size of each drawdown may be up to \$3,000,000 in a five-day drawdown period or up to \$4,500,000 if the average daily dollar trading volume of the Company's common stock increases to \$7,500,000. The Company is under no obligation to draw down funds, and as of February 28, 2002, has drawn \$7,250,000 under this agreement. The Company is currently unable to raise funds through this agreement because its recent stock prices have been below the minimum price specified in the agreement. We intend, if able to do so, to draw from this facility in fiscal 2002.

Management's Discussion and Analysis of Financial Condition and Results of Operations January 31, 2002 (Continued)

We plan to continue financing our operations, until we are profitable, through sales of equity and debt securities, bank borrowings and leasing arrangements. On March 11, 2002, we filed a \$30,000,000 common stock shelf registration statement with the SEC to facilitate future financings. The registration statement has been declared effective by the SEC. We will also explore licensing and partnering arrangements where appropriate. We have not been profitable since inception and had an accumulated deficit of \$345,537,000 as of January 31, 2002. We will continue to generate losses for the next several years.

We plan to spend approximately \$6,000,000 in fiscal 2002 and approximately \$5,000,000 in fiscal 2003 on capital projects for our existing facilities. The fiscal 2002 planned expenditures are included in the cash requirements for fiscal 2002 identified above.

As of October 31, 2001, we had net operating loss carryforwards of approximately \$195,100,000 to offset future federal and state taxable income through 2021. Due to the degree of uncertainty related to the ultimate realization of such prior losses, no benefit has been recognized in our financial statements as of January 31, 2002. Utilization of such losses in future years may be limited under the change of stock ownership rules of the Internal Revenue Service.

Quantitative and Qualitative Disclosure About Market Risk

The Company currently does not have any foreign currency exchange risks, with the exception of negligible exchange fluctuations associated with expenses for clinical trial and regulatory activities outside of the United States. Biopure sells Oxyglobin to its European distributors and plans to sell Hemopure to its South African distributor in 2002 in U.S. dollars. The customers bear the risk of foreign currency exchange fluctuation. Dramatic fluctuations in exchange rates could result in either increases or decreases in unit sales as the effective unit price to the customer varies. The Company invests its cash and cash equivalents in high-grade commercial paper and money market funds. These investments are subject to interest rate risk. However, due to the nature of the Company's short-term investments, it believes that the financial market risk exposure is not material.

# BIOPURE CORPORATION Part II — Other Information January 31, 2002

## Item 1. Legal Proceedings

As of March 15, 2002, Biopure and its Chairman and Chief Executive Officer were named as defendants in five related cases filed on February 5, 2002, February 22, 2002, March 15, 2002 and two on March 12, 2002, respectively, in the U.S. District Court for the District of Massachusetts (the "Court") by alleged purchasers of Biopure's common stock, purporting to be class actions. The lawsuits claim that Biopure violated the federal securities laws by publicly disseminating materially false and misleading statements regarding the anticipated timing of a biologic license application Biopure expected to make to the U.S. Food and Drug Administration, resulting in the artificial inflation of Biopure's common stock price during the purported class period between May 8, 2001 through December 6, 2001. The complaints do not specify the amount of alleged damages plaintiffs seek to recover. Defendants have filed motions to dismiss the complaints and believe that the lawsuits are without merit and intend to defend them vigorously.

## Item 2. Changes in Securities and Use of Proceeds

Warrants to purchase 66 shares of Class A Common Stock were exercised on November 26, 2001, during the first quarter of fiscal 2002, for aggregate proceeds to the Corporation of \$800. The Corporation relied on Section 4(2) of the Securities Act of 1933 and Regulation D under the Securities Act of 1933 in issuing shares upon the exercise of warrants, since the offering and sale of these shares did not involve a public offering.

During the first quarter of fiscal 2002, Biopure issued an aggregate of 516,531 shares of its Class A Common Stock to Société Générale for total proceeds of \$7,250,000 by drawing on its equity line of financing with Société Générale. Biopure relied on Section 4(2) of the Securities Act of 1933 in issuing these shares, since the offering and sale of these shares to Société Générale did not involve a public offering. These transactions occurred as follows:

| Date of Issuance  | Number of Shares | Proceeds    |
|-------------------|------------------|-------------|
| December 21, 2001 | 203,538          | \$3,000,000 |
| January 3, 2002   | 128,941          | \$1,770,000 |
| January 11, 2002  | 150,942          | \$2,040,000 |
| January 18, 2002  | 33.110           | \$ 440.000  |

# Item 6. Exhibits and Reports on Form 8-K

- (a) The exhibits are listed in the accompanying Exhibit Index.
- (b) A report on Form 8-K was filed on December 6, 2001.
- (c) A report on Form 8-K was filed on January 18, 2002.
- (d) A report on Form 8-K was filed on March 13, 2002.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOPURE CORPORATION

Date: March 18, 2002 By: /s/ Francis H. Murphy

Francis H. Murphy

Duly authorized officer of the Registrant and

Chief Financial Officer

# EXHIBIT INDEX

| Number | Description                                 |
|--------|---|
| 15     | Acknowledgement Letter of Ernst & Young LLP |
| 99     | Risk Factors                                |